MAR - 1 2001

K003715

CoolTouch Corporation
CoolTouch Nd:YAG Laser System
510(k) Premarket Notification

510(k) SUMMARY

Submitter:	CoolTouch Corporation
Address:	9085 Foothills Boulevard Roseville, CA 95747
Contact Person:	Donald V. Johnson Director of Regulatory and Quality Affairs
Telephone:	(916) 677-1900
Facsimile:	(916) 677-1919
Date Prepared:	November 27, 2000
Device Trade Name:	CoolTouch Nd:YAG Laser System CoolTouch-II Nd:YAG Laser System
Common Name:	Nd: YAG Pulsed Surgical Laser
Classification Name:	Laser Surgical Instrument. 21 C.F.R. § 878.4810
Legally Marketed Predicate Device:	New Star Lasers, Inc. Model 130 Nd:YAG Surgical Laser System (K962791).
Description of the CoolTouch Nd:YAG Laser Systems:	The CoolTouch Nd:YAG Laser Systems are ND:YAG lasers producing laser emission at 1320 nm. The lasers consist of three interconnected sections: The cabinet, which houses the power supply, cooling system, microcontroller and the laser, the fiber optics, and the handpiece.
Intended use of CoolTouch Nd:YAG Laser Systems:	The CoolTouch Nd:YAG Laser Systems are indicated for the treatment of periorbital wrinkles.
Nonclinical Performance Data:	None
Clinical Performance Data:	Clinical trials produced results that indicate that that CoolTouch Nd:YAG Laser System is effective in the treatment of periorbital wrinkles.
Conclusion:	The CoolTouch Nd:YAG Laser Systems are indicated for the treatment of periorbital wrinkles.
Additional Information:	None requested at this time

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2001

Mr. Donald V. Johnson
Director of Regulatory
and Quality Affairs
CoolTouch Corporation
9085 Foothills Boulevard
Roseville, California 95747

Re: K003715
Trade Name: CoolTouch Nd:YAG Laser System
CoolTouch-II Nd:YAG Laser System
Regulatory Class: II
Product Code: GEX
Dated: November 27, 2000
Received: December 1, 2000

Dear Mr. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K003715

Device Name: CoolTouch Corporation "CoolTouch"and "CoolTouch-II" Nd:YAG Laser Systems

Indications for Use:

The CoolTouch Nd:YAG Laser Systems are indicated for the treatment of periorbital wrinkles.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003715